



CDC Zika IMS Sustaining the Zika Response in 2017 Laboratory Task Force

Wednesday, 15 March 2017

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Opening Remarks

OVERVIEW

- Opening Remarks
 - 2016 Zika Lessons Learned
 - Updates to Zika Guidance
 - Task force recommendations for jurisdictional and CDC actions for 2017
 - Q&As
 - Closing Remarks
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Laboratory Task Force

Why Important – Continental US

- ❑ **Continental US will continue to have travelers who go to areas with Zika virus**
- ❑ **Further local transmission of Zika virus is still a potential; however, the extent is unknown**
- ❑ **Zika diagnostic test performance continues to be limited by cross-reactivity to other flaviviruses**

Successes

- ❑ **CDC-developed MAC-ELISA (February 26, 2016) and Trioplex rRT-PCR (March 17, 2016) tests receive first FDA EUA to diagnose Zika virus infection**
- ❑ **CDC continues to manufacture and distribute reagents for these assays domestically and internationally**
- ❑ **CDC laboratories provide confirmatory testing and surge capacity for Zika virus**

| Laboratory | Number of Specimens Received | Number of Specimens Tested by rRT-PCR | Number of Specimens Tested by Zika IgM MAC-ELISA |
|-----------------------------|------------------------------|---------------------------------------|--|
| CDC-Atlanta | 5,023 | 3,464 | 2,827 |
| CDC-Fort Collins | 18,262 | 3,926 | 15,571 |
| CDC-San Juan | 81,667 | 45,136 | 48,015 |
| Laboratory Response Network | 60,788 | 25,439 | 35,349 |
| Total | 165,2692 | 77,965 | 101,762 |

Concerns

- ❑ **Limited data on viral persistence and effect on testing algorithms**
- ❑ **Specificity of diagnostic assays**
 - In-house evaluation of 3 commercial assays with MAC-ELISA as gold standard

| Manufacturer | Sensitivity | Specificity |
|-----------------------|-------------|-------------|
| InBios (EUA approved) | 82% | 85% |
| NovaTec NovaLisa | 70% | 98% |
| Euroimmun | 72% | 95% |

- ❑ **Usefulness of PRNT**
 - Cross reactivity due to past flavivirus infections
- ❑ **Turnaround time from sample receipt to when results reach physicians**
 - Discussions ongoing to pursue Health Level-7 (HL7)messaging to decrease time from test completion to results being available to a physician

Zika Virus Laboratory Priorities, 2017

- ❑ **Continue to provide Zika virus subject matter expert and reference laboratory support in Fort Collins; surge planning for upcoming season in progress**
- ❑ **Maintain surge laboratories for Zika diagnostic testing in Atlanta**
- ❑ **Assist state and territorial laboratories, as needed**
- ❑ **Refine performance of diagnostic assays inclusive of assessing the value of whole blood and urine in molecular diagnostics**
- ❑ **Consider updates to the testing algorithm to allow increased flexibility and to simplify as appropriate**
- ❑ **Assist as needed in moving testing to commercial laboratories**
- ❑ **Continue to conduct new research**

Plans - Move testing to commercial laboratories

- ❑ **Early in response CDC entered into agreements with the 4 nation-wide commercial laboratories**
 - Provided MAC-ELISA reagents free of charge to encourage testing until additional serologic assays achieved EUA approval
 - Challenges with reporting and commercial lab performance
- ❑ **Movement of testing will decrease surge needs for CDC laboratories**
 - 12 PCR assays currently FDA EUA approved (including Trioplex)
 - 2 IgM assay currently FDA EUA approved (including MAC-ELISA)

Plans - New Research: Improvement of Molecular and Serologic Diagnostic Tools for Zika Virus (all CDC laboratories)

- ❑ **Improve sensitivity of high-throughput rRT-PCR by specimen volume or type**
 - Studies ongoing to evaluate serum, whole blood, and urine to evaluate sensitivity of each
- ❑ **Develop a Zika virus multiplex bead assay (IgM/IgG)**
 - Investigation of more specific antibodies
- ❑ **Develop-rapid and specific IgM diagnostic test that uses mass spectrometry**
- ❑ **Refine recombinant antigens in testing platforms to eliminate the need for inactivation of live virus**

Why Important – Puerto Rico

- ❑ **Epidemic transmission**
 - Almost 38,000 confirmed cases (102,000 tested)
 - Peak of epidemic during September 2016
- ❑ **Rate Zika-associated of birth defects will not be known until summer 2017**

Upcoming Transmission Season – Puerto Rico

- ❑ **Likely will start in May**
- ❑ **Likely will be less intense for Zika, but could be high for dengue or chikungunya due to varying seasonality**

Concerns – Puerto Rico

- ❑ Existing PR requirement to test pregnant women in each trimester of pregnancy (30,000 pregnancies/year)
- ❑ Co-circulation of dengue and chikungunya viruses requires complex testing algorithm for symptomatic cases
- ❑ PRNTs are impractical and uninformative because of the high volumes of samples and the previous exposure of the population to dengue
 - Confirmatory testing of PCR neg/IgM pos is not feasible

2017 Anticipated Plans – Puerto Rico

- ❑ **CDC Dengue laboratory (Capacity = 1500 samples/month) to support PRDH arbovirus surveillance needs**
- ❑ **Surge Plan for 2017**



- ❑ **Validate and evaluate CDC's commercial diagnostic tests for Zika and provide recommendations to Puerto Rico Department of Health (PRDH)**

*BCEL - Biological and Chemical Emergencies Laboratory

2017 Anticipated Plans – Puerto Rico

- ❑ **Supports testing for Zika-related epidemiologic and clinical assessments as needed. For example**
 - Guillain-Barre Syndrome surveillance
 - Screening of pregnant women
 - Cross reactivity in serologic tests
 - Virus persistence in body fluids
 - Testing of placenta or newborns
- ❑ **Improve automation and throughput for Zika, dengue and chikungunya testing**

Closing Remarks

| TELECONFERENCE OVERVIEW | DATE/TIME/LOCATION |
|---|---|
| Laboratory Task Force Eddie Ades, Robert Lanciotti, Christy Ottendorfer | Wed 3/15/2017 / 2pm–3pm EDT - Domestic Wed 3/15/2017 / 5 pm–6 pm EDT - Islands Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Joint Information Center/Communications Erin Connelly | Wed 3/22/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Epidemiology Task Force Stacey Martin, Carolyn Gould | Thurs 3/23/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Vector Issues Team Janet McAllister, Audrey Lenhart | Tues 3/28/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Policy and Partnerships Sue Visser, Melody Stevens | Wed 3/29/2017 / 1:30pm–2:30pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Pregnancy and Birth Defects Task Force (including surveillance) Peggy Honein, Dana Meaney-Delman, Suzanne Gilboa | Wed 3/29/2017 / 3pm–4pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Blood Safety Task Force Sustainment Strategy Discussions Koo Chung, Matt Kuhnert, Craig Hooper | Thurs 3/30/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |
| Medical Investigations Team Sustainment Strategy Discussions Maleeka Glover | Thurs 3/30/2017 / 3:30pm–4:30pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430 |

Thank You!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

